

We claim:

1. A diagnostic or prognostic assay for cancer, comprising:

- (a) obtaining a tissue sample from a test tissue;
(b) performing a methylation assay on DNA derived from the tissue sample,

5 wherein the methylation assay determines the methylation state of a CpG dinucleotide within a DNA sequence of the DNA, and wherein the DNA sequence is a sequence selected from the group consisting of sequences of SEQ ID NOS:1-103, sequences having a nucleotide sequence at least 90% identical to sequences of SEQ ID NOS:1-103, CpG island sequences associated with sequences of SEQ ID NOS:1-103, CpG island sequences associated with
10 sequences having a nucleotide sequence at least 90% identical to sequences of SEQ ID NOS:1-103, and combinations thereof, wherein the CpG island sequence associated with the sequence of the particular SEQ ID NO is that contiguous sequence of genomic DNA that encompasses at least one nucleotide of the particular SEQ ID NO sequence, and satisfies the criteria of having both a frequency of CpG dinucleotides corresponding to an
15 Observed/Expected Ratio >0.6, and a GC Content >0.5; and

(c) determining a diagnosis or prognosis based, at least in part, upon the methylation state of the CpG dinucleotide within the DNA sequence.

2. The diagnostic or prognostic assay of claim 1 wherein the DNA sequence is a sequence selected from the group consisting of CpG island sequences associated with
20 sequences of SEQ ID NOS:1-103, CpG island sequences associated with sequences having a nucleotide sequence at least 90% identical to sequences of SEQ ID NOS:1-103, and combinations thereof.

3. The diagnostic or prognostic assay of claim 2 wherein the DNA sequence is a sequence selected from the group consisting of CpG island sequences associated with
25 sequences of SEQ ID NOS: 2, 4, 6, 7, 9-16, 19, 20, 22-33, 35-43, 48, 51-55, 59, 60, 64, 71, 76, 78-81, 84 and 87-90, and combinations thereof.

4. The diagnostic or prognostic assay of claim 1 wherein the methylation assay procedure is selected from the group consisting of MethyLight, MS-SNuPE, MSP MCA, COBRA, and combinations thereof.

30 5. The diagnostic or prognostic assay of claim 1 wherein the methylation state of the CpG dinucleotide within the DNA sequence is that of hypermethylation, hypomethylation or normal methylation.

6. The diagnostic or prognostic assay of claim 1 wherein the cancer is selected from the group consisting of bladder cancer, prostate cancer, colon cancer, lung cancer, renal
35 cancer, leukemia, breast cancer, uterine cancer, astrocytoma, glioblastoma, and neuroblastoma.

7. A kit useful for the detection of a methylated CpG-containing nucleic acid
comprising a carrier means containing one or more containers comprising:

Sub
A2
copied

(a) a container containing a probe or primer which hybridizes to any region of a sequence selected from the group consisting of SEQ ID NOS:1-103, and sequences having a nucleotide sequence at least 90% identical to sequences of SEQ ID NOS:1-103; and

(b) additional standard methylation assay reagents required to affect detection of methylated CpG-containing nucleic acid based, at least in part, on the probe or primer.

8. The kit of claim 7, wherein the additional standard methylation assay reagents are standard reagents for performing a methylation assay from the group consisting of MethyLight, MS-SNuPE, MSP MCA, COBRA, and combinations thereof.

9. The kit of claim 7, wherein the probe or primer comprises at least about 12 to 15 nucleotides of a sequence selected from the group consisting of SEQ ID NOS:1-103, and sequences having a nucleotide sequence at least 90% identical to sequences of SEQ ID NOS:1-103.

✓ 10. An isolated nucleic acid molecule comprising a methylated or unmethylated polynucleotide sequence selected from the group consisting of SEQ ID NO:1, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:10, SEQ ID NO:12, SEQ ID NO:13, SEQ ID NO:18, SEQ ID NO:24, SEQ ID NO:25, SEQ ID NO:32, SEQ ID NO:34, SEQ ID NO:37, SEQ ID NO:38, SEQ ID NO:42, SEQ ID NO:44, SEQ ID NO:51, SEQ ID NO:52, SEQ ID NO:62, SEQ ID NO:64, SEQ ID NO:65, SEQ ID NO:68, SEQ ID NO:69, SEQ ID NO:70, SEQ ID NO:71, SEQ ID NO:74, SEQ ID NO:76, SEQ ID NO:82, SEQ ID NO:83, SEQ ID NO:84, SEQ ID NO:86, SEQ ID NO:90, SEQ ID NO:92, SEQ ID NO:97, and SEQ ID NO:100. 3

11. The nucleic acid of claim 10, wherein the nucleic acid is methylated.

12. The nucleic acid of claim 10, wherein the nucleic acid is unmethylated.